

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0695096	(X3) Date Survey Completed 01/20/2021
Name of Provider or Supplier Ferrara Dermatology Clinic	Street Address, City, State 20045 Mack Ave, Grosse Pointe Woods, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with the Office Manager (OM), the laboratory failed to ensure written competency policies were followed for 3 (#1 - #3) of 3 testing personnel performing the mycology potassium hydroxide (KOH) and parasitology testing. Findings include: 1. A record review of the competency assessments revealed for 3 (#1 - #3) of 3 testing personnel the policy was not followed in 2020. 2. The competency assessments in 2020 lacked the documentation of the six requirements from subpart M as follows for the mycology and parasitology testing: a. Direct observations of routine patient test performance, patient preparation, specimen handling, processing, and testing. b. Monitoring the recording and reporting of patient test results. c. Review of test results, worksheets, quality control records, proficiency testing results, and preventive maintenance. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed samples. f. Assessment of problem solving skills. 3. A interview on 1/20/21 at 10:43 am, the OM confirmed the competency policy was not followed to assess the six requirements from Subpart M in 2020. ***Repeat Deficiency from 4/08/16 and 5/14/18 surveys***</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Office Manager (OM), the laboratory failed to perform and document the daily (each day of use) cleaning of the microscope for 6 (#2, #5 - #10) of 10 patient charts audited for 2 years. Findings include: 1. A record review of the "Microscope Daily Log" revealed for 6 of 10 patient charts audited the daily microscope cleaning was not performed and documented as follows: a. 2/04/19 b. 12/10/19 c. 2/25/20 d. 5/22/20 e. 9/08/20 f. 11/10/20 2. A record review of the procedure "Quality Control Procedure Ectoparasites (KOH)" states in step 4, "Each time that a specimen is examined the microscope daily log is filled out to document the preparation of the microscope." 3. A interview on 1/20/2021 at 10:43 am, the OM confirmed the above maintenance tasks were not performed and documented. ***Repeat Deficiency from the 5/14/18 survey***